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EXAMINER				
EBRAHIM, NABILA G				
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/623,110
Filing Date: July 18, 2003
Appellant(s): SAGMAN ET AL.

Raymund F. Eich
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/14/2008 appealing from the Office action mailed 11/19/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,593,197

Erlanger et al.

7-2003

CA Haberzettl, "Nanomedicine: destination or Journey?" Nanotechnology 13 (Jul. 04 2002 R9-R13.

Williams JS et al. "Targeting and therapy of human Xenografts in vivo using radiolabeled antibodies", Int J Radat Oncol Biol Phys. (Sep;19, 1990) pp. 633-42

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6-10 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlanger et al. US 6593137 (Erlanger) in view of CA Haberzettl, Nanomedicine: destination or Journey? Nanotechnology 13 (2002) R9-R13 (hereinafter Haberzettl) and further in view of Williams JA et al. (Targeting and therapy of human xenografts in vivo using radiolabeled antibodies.) Int J Radiat Oncol Biol Phys. 1990 Sep;19(3):633-42 (hereinafter "Williams").

Erlanger discloses a therapeutic antibody which is specific for a fullerene or derivative thereof, wherein the fullerene is selected from the group consisting of a fullerene carbon compound having from 20 to 540 carbon atoms, (col. 2, lines 15-18). Erlanger discloses that the possibility of covalent linkage between fullerenes and a specific monoclonal antibody is raised and can be tested (col. 20, lines 4-6), and explains the way of testing the linkage in (col. 20, Lines 18+).

Erlanger used a fullerene specific antibody, however, the reference does not disclose an antibody, which recognizes an antigen.

Haberzettl teaches Buckyballs, fullerenes, nanotubes is the short name for a molecule composed of 60 atoms of carbon arranged in a hollow sphere developing nanobots, successful drug delivery architectures will be enhanced by allowing them to target a particular tissue or organ. The most likely mechanisms to be employed are based on antigen/antibody interactions or binding of target molecules to membrane-bound receptors. Haberzettl discloses that drugs are being encapsulated in a variety of nanoparticles to enhance effectiveness and decrease side effects or to overcome solubility and toxicity issues, these drugs such as nanoparticle-stabilized doxorubicin.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a fullerene tube attached to an antibody that recognizes an antigen and add a drug such as doxorubicin to enhance the treatment of a disease and reduce the side effects of the drug as disclosed by Haberzettl.

Erlanger and Haberzettl did not disclose the Ab comprising an antigen-binding site selected from the group recited in claim 4.

Williams disclosed radiolabeled antibodies provide a potential basis for selective radiotherapy of human gliomas. Williams used monoclonal antibodies QCI054 and ZME018, which define a tumor-associated and a second melanoma-associated antigen, respectively, demonstrate positive immunoperoxidase staining of the tumor.

Because William disclosed the effectiveness of ZME-018 in treating cancers, it would have been obvious to a man of ordinary skill in the art at the time the invention was made to use ZME-018 with fullerene to therapeutically target the cancer site. The expected result would be a composition that comprises a fullerene, an anti-body, which recognizes an antigen, and a

radioisotope to be used in a method of treating a cancer.

Instant claim 14 recite the treatment of oxidative stress disease, since Williams include gliomas in his reference, it is recognized that glioma is an oxidative stress disease as evidenced by KL Tsai et al. (Mechanism of oxidative stress-induced intracellular acidosis in rat cerebellar astrocytes and C6 glioma cells), The Journal of Physiology, Vol. 502, Issue 1 161-174, 1997.

The three references did not disclose the doses for using these compounds to treat cancers or oxidative stress syndrome. However, it is within the capabilities of a person having ordinary skill in the art to adjust the dose according to the severity of the condition and the needs of the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a fullerene tube attached to an antibody that recognizes an antigen and add a drug such as doxorubicin to enhance the treatment of a disease as disclosed by Haberzettl, the artisan would be further motivated to use ZME-018 with fullerene to therapeutically target the cancer site because William disclosed the effectiveness of ZME-018 in treating cancers. The expected result would be a composition that comprises a fullerene, an anti-body, which recognizes an antigen, and a radioisotope to be used in a method of treating a cancer or an oxidative stress disease.

(10) Response to Argument

Appellant argues that: Haberzettl's is speculative and hypothetical teachings, ungrounded with any reference to the chemistry of buckyballs, fullerenes, nanotubes, functionalizations thereof, targeting mechanisms, payloads, and the combination thereof into useful structures, give the person of ordinary skill in the art no motivation to combine Haberzettl with either or both of Erlanger or Williams.

This was not found persuasive because Appellant's claims recite a composition and method of using the composition. The claims do not require a method of making or loading. The prior art disclose the composition as a therapeutic antibody which is specific for a fullerene or derivative thereof, wherein the fullerene a carbon compound having from 20 to 540 carbon atoms, the covalent linkage between fullerenes and a specific monoclonal antibody is raised and can be tested and explains the way of testing the linkage. Habertzettl teaches Buckyballs, fullerenes, nanotubes is a molecule composed of 60 atoms of carbon arranged in a hollow sphere developing nanobots, successful drug delivery architectures will be enhanced by allowing them to target a particular tissue or organ. The most likely mechanisms to be employed are based on antigen/antibody interactions or binding of target molecules to membrane-bound receptors. An example of these drugs is nanoparticle-stabilized doxorubicin. Note that the document discloses the targeting mechanisms and the payload in the paragraph bridging between the two columns in **pages R10 and R11** in a way sufficient to reject the instant claims. For example the document teaches payloading disclosing that the simplest payload is a currently available therapeutic agent formulated into nanoarchitecture. More complex payload would be a functional cell developed as a method of encapsulating hormone producing cells within a nanoarchitecture having well defined and controlled pore size. The reference also discloses combining therapeutic agents with targeted nanoparticles in which the payload could be used to enhance or inhibit a physiological or biochemical process and gives examples of the National Cancer Institute that used this combination.

Appellant argues that: In summary, Habertzettl's speculative and hypothetical teachings, ungrounded with any reference to the chemistry of buckyballs, fullerenes, nanotubes, functionalizations thereof, targeting mechanisms, and the combination thereof into useful

structures, give the person of ordinary skill in the art no motivation to combine Haberkettl with either or both of Erlanger or Williams.

This was not found persuasive because as noted hereinabove, the motivation of combining Haberkettl is to enhance the treatment of a disease and reduce the side effects of the drug or to overcome solubility and toxicity issues as disclosed by Haberkettl (page R10, 2.1).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nabila G Ebrahim/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617